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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,189	10/06/2000	VOLKER HEINRICH	02-101510US	6794

22798 7590 03/22/2002

LAW OFFICES OF JONATHAN ALAN QUINE  
P O BOX 458  
ALAMEDA, CA 94501

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/22/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/685,189

Applicant(s)

HEINRICHS ET AL.

Examiner

Janet L Andres

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 31-63,105,120,121,124-132 and 147-157 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-63,105,120,121,124-132 and 147-157 is/are rejected.
- 7) ☒ Claim(s) 31-34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group II and species election of SEQ ID NO: 41 without traverse in paper no. 10 is acknowledged. The restriction requirement is made final. Applicant has cancelled non-elected claims and added new claims 149-157. Claims 31-63, 105, 120, 121, 124-132, and 147-157 are pending in this application. The claims are examined in light of the species election of SEQ ID NO: 41.

### ***Specification***

2. The disclosure is objected to because of the following informalities: The continuing data are incorrect. The instant application is a continuation of 09/415183. Further, the consensus sequence on p. 3 and 22 and the sequences on p. 43 require sequence identification numbers.

Appropriate correction is required.

### ***Claim Objections***

3. Claims 31-33 are objected to as depending from a cancelled claim.

4. Claim 34 is objected to because the claimed sequence is not referred to by the identification number of an entered sequence. See MPEP §2422.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1646

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 31-63, 105, 120, 121, 124-132, and 147-157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stabinsky, U.S. Patent No. 4695623, September, 1987. Claims 31-53, 60-63, 105, 120, 121, 130, 131, and 147-157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blatt et al., J. Interferon and Cytokine Res. 1996, vol. 16, pages 489-499. Stabinsky teaches a consensus interferon sequence. This sequence was derived by a comparison of the known interferon alpha sequences. In Figure 2, Stabinsky presents an alignment of these sequences and the derived consensus sequence. This alignment is more clearly shown by Blatt et al., which teaches a similar comparison in Table 1, pages 492-493. Nearly all of the sequences claimed in the instant application can be derived by taking the sequence of consensus interferon and substituting a corresponding amino acid or amino acids from one of the sequences from which it was derived. The sequence of claim 34 does include possible amino acid substitutions not found in the sequences taught by Stabinsky or Blatt et al. However, these substitutions are optional; each set of alternatives includes one or more amino acids found in the corresponding position of a naturally occurring interferon alpha. Further, Stabinsky teaches in column 33, lines 45-47, that "consensus human leukocyte interferon will ordinarily include all known common amino acids of all subtypes", in column 34, lines 11-16 that "polypeptides lacking one of more

Art Unit: 1646

internal or terminal residues or including internal or terminal residues having no counterpart in any subtype would be considered analogs of human consensus leukocyte interferon” and in, column 42, line 10, a “genus”. Thus, Stabinsky clearly contemplates variations of the consensus sequence taught in Figure 2. Stabinsky additionally teaches antiviral activity and increased activity (column 41, lines 13-39, and column 42, lines 1-6) as well as pharmacological use and tagged polypeptides (column 42, lines 14-29). Blatt et al. teaches pharmacological use on pages 494-497; Blatt et al. fails to teach the modifications of claims 54-59, 124-129, and 132.

Thus it would have been *prima facie* obvious to one of ordinary skill to take the known consensus sequence and change selected to amino acids to one of the other options indicated by the alignment of sequences shown in Figure 2 of Stabinsky and Table 1 of Blatt et al. with the expectation that the resulting polypeptide would function as an interferon alpha. One of ordinary skill would further have expected some of these options to have enhanced activity, since such enhancement is taught by Stabinsky.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 31 and 37-40 rejected under 35 U.S.C. 102(b) as being anticipated by Stabinsky and Blatt et al., cited above. These claims are drawn to polypeptides derived from sequences identified by stringent hybridization. Such a process would identify the known interferons taught by Stabinsky and Blatt et al. and thus the claims are anticipated by these teachings.

*Claim Rejections - 35 USC § 112*

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 31, 32, 37, 40, 41, 45-49, 51, 52, 54-63, 105, and 124-132 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to sequences comprising fragments, sequences comprising molecules identified by hybridization, or sequences comprising entities identified by antibodies. There are no limitations requiring that the claimed molecules function as interferons. Thus the claims encompass a genus that includes molecules of undefined composition and function. There are no required structural features or conserved regions or other identifying characteristics set forth as commonly possessed by members of the claimed genus. Thus, without a functional limitation or defined structural characteristics, one of skill in the art would not be able to recognize the individual members of the genus. One of skill in the art would thus not conclude that Applicant was in possession of the genus of sequences comprising fragments and other variants of the disclosed sequences as broadly claimed.

11. Claims 31, 32, 37, 40, 41, 45-49, 51, 52, 54-63, 105, and 124-132 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for variants of consensus interferon comprising combinations of the variants from which it was derived, and conservative substitutions thereto, does not reasonably provide enablement for sequences

Art Unit: 1646

comprising fragments, sequences comprising molecules identified by hybridization, or sequences comprising entities identified by antibodies with no functional limitations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has described defined variants of consensus interferon. However, applicant has not described the characteristics of these sequences so that one of skill in the art could predictably identify sequences comprising undefined variants that would have the same characteristics. Applicant has not described the properties or characteristics of the sequences that are required for function. Thus, the essential characteristics of these variants are not described. Further, while recombinant techniques are available, it is not routine in the art to screen large numbers of nucleic acids that might potentially encode such proteins where the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structural features would result in interferon function, in order to practice the invention commensurate with the scope of the claims without undue experimentation..

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is an improper Markush group. It is not clear whether the sequence is selected from the sequences individually, or from a, b, and c, which are groups consisting of the

Art Unit: 1646

individual sequences. Thus one of skill in the art would not know what groups Applicant intended to claim.

14. Claims 31, 33, 37-40, 54-62, and 120-148 are rejected under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of "highly stringent conditions". This term is not so defined in the specification so that one of skill in the art would be able to determine which molecules were included and which were not: there are no salt or pH limitations in the conditions set forth in the definition on p. 44 and thus there are no limitations on what sequences would be encompassed..

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that




Art Unit: 1646

sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
March 21, 2002

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600